K111252

510(k) Summary
per 21 CFR §807.92

JUN - 2 2011

Sponsor:	Boston Scientific Corporation One Boston Scientific Place Natick MA 01760
Contact Person:	Holly Ramirez
Phone Number:	763-494-2113
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Prepared:	May 2, 2011
Trade Name:	ACUITY™ Cut-Away™ Guide Catheter
Common Name:	Percutaneous Guide Catheter
Classification:	II
Product Code:	DQY 21 CFR 870.1250

Predicate Device: ACUITY™ Break-Away™ Guide Catheters (K093969; March 05, 2010) and RAPIDO Cut-Away Guiding Catheter (K031459, July 23, 2003).

Device Description:

The ACUITY™ Cut-Away™ Guide Catheters are designed for venous use to aid in the selective placement of cardiac resynchronization therapy (CRT) implantable venous leads in the cardiac vasculature.. The catheter shafts are comprised of an inner liner of polytetrafluoroethylene (PTFE), a reinforcing layer of 304V stainless steel braid, and an outer jacket of radiopaque bismuth subcarbonate-loaded polyether block amide (PEBAX). This construction creates a thin catheter wall that is pushable, steerable, torqueable, and kink-resistant. The stiffness of the PEBAX jacket changes along the catheter from more stiffness proximally to less distally.

A radiopaque PEBAX tip is thermally attached to the distal end of the guide catheter shaft. This tip consists of a layer of tungsten loaded PEBAX co-extruded with an outer layer of bismuth subcarbonate-loaded PEBAX.

A PEBAX hub is attached to the proximal end of the shaft. One wing of the hub is used for the orientation of the curve shape relative to the hub.

The approximate working length of the catheter is 69-74 cm.

Intended Use

The ACUITY™ Cut-Away™ catheters are intended to access the coronary venous system, and may be used in dual-catheter delivery. The catheter serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.

Substantial Equivalence

The ACUITY™ Cut-Away™ Guide Catheter design, materials, manufacturing process and intended use are substantially equivalent to the ACUITY™ Break-Away™ Guide Catheter (K093969) and the RAPIDO™ Cut-Away Guiding Catheter (K031459).

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Summary of Non-Clinical Testing

Design verification and validation testing, including mechanical bench testing, and animal testing, was performed to verify the performance and usability of the ACUITY™ Cut-Away™ Guide Catheter remains substantially equivalent to both predicate devices. Biocompatibility, sterility, and packaging testing were also performed to verify the overall safety and efficacy of the device.

Specifically the following design verification and validation testing was performed:

- Hub Separation
- Hub Cutting
- Hub Internal Diameter
- Particulates
- Biocompatibility Testing
  - Cytotoxicity
  - Sensitization
  - Irritation Or Intracutaneous Reactivity
  - Systemic Toxicity (Acute)
  - Hemocompatibility
  - Latex
  - USP Physicochemical
- Usability Of Multiple Catheter Shapes And Lengths
- Compatibility With Accessories And Adjunctive Devices
- Torquability
- Pushability & Shaft Stiffness
- Product Marking And Identification
- Catheter Removal
- Product Integrity
- Radiopacity
- Ease Of Removal Of Device And Accessories From Packaging

Summary of Clinical Testing

Clinical Evaluation was not required for these devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Boston Scientific Corporation
c/o Ms. Holly Ramirez
Regulatory Affairs Specialist
One Boston Scientific Place
Natick, MA 01760

JUN - 2 2011

Re: K111252
Trade/Device Name: ACUITY™ Cut-Away™ Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 2, 2011
Received: May 3, 2011

Dear Ms. Ramirez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. A. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111252

Device Name: ACUITY™ Cut-Away™ Guide Catheter

Indications For Use:

The ACUITY™ Cut-Away™ Lead Delivery System is intended to access the coronary venous system and may be used alone (8F or 6F) or in a dual catheter delivery (8F and 6F). The system serves as a conduit for the delivery of contrast medium and devices, including implantable coronary venous leads, introduced into the coronary venous system.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. J. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

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